## REMARKS

Claims 35-39 and 70-72 are pending.

The undersigned thanks the Examiner for the telephone interviews of May 20, 2009 and June 17, 2009 in which the claims of this application and the claims of related U.S. Patent Application Serial No. 12/141,489 were discussed. Agreement was not reached in the interviews.

### The rejection under 35 U.S.C. §112

Claims 35-39 and 70-72 were rejected as being indefinite. According to the Office Action, the words "dosing unit" in claim 35 makes it unclear whether the claim is directed to a compound or to a pharmaceutical formulation.

The Applicants respectfully traverse this rejection.

The presence of the words "dosing unit" in claim 35 does not transform claim 35 from a compound claim to a pharmaceutical formulation or a pharmaceutical composition claim. Instead, "dosing unit" is used in claim 35 to indicate the amount of the recited compound that is within the scope of claim 35.

The words "dosing unit" appear in the phrase "sufficient for a dosing unit." This phrase immediately follows the word "amount" and refers back to, and thus modifies, the word "amount" by specifying a particular value for "amount." Consistent with the grammatical structure of this claim, the phrase "sufficient for a dosing unit" could be replaced by a phrase that specifies a different amount, e.g., "of at least 3 mg." If that were done, the entire limitation

added to claim 35 by the Amendment filed April 1, 2009 would read "wherein the free base is present in an amount of at least 3 mg." When this is understood, it is clear that "dosing unit" should not be interpreted by plucking it out of the context of the phrase "sufficient for a dosing unit" and interpreting it on its own. It must be understood as part of that phrase, and that phrase must be understood as specifying an amount, not as changing the overall claim from a compound claim to a pharmaceutical formulation or a pharmaceutical composition claim. This is especially clear when one considers that claim 35 does not mention pharmaceutically acceptable carriers or excipients, which are typically recited in pharmaceutical formulation or pharmaceutical composition claims.

In view of the grammatical features of claim 35 discussed above, and the lack of any mention of pharmaceutically acceptable carriers or excipients, interpreting claim 35 as being directed to a pharmaceutical formulation or a pharmaceutical composition is not reasonable.

In view of the above, it is respectfully requested that this rejection be withdrawn.

**The rejection under 35 U.S.C. §102(b)**

Claims 35-39 and 70-72 were rejected as being anticipated by WO 99/58478 (Meese).

The Applicants respectfully traverse this rejection. In the Amendment filed April 1, 2009, the Applicants explained that Meese does not enable the production of a compound as recited in claim 35 that meets the limitations of both purity (above 97% by weight) and amount (sufficient for a dosing unit) recited in claim 35.

With respect to the limitation "amount sufficient for a dosing unit," the Office Action, at page 3, stated that Meese inherently meets this limitation because "the term 'dosing unit' as defined in the instant specification is open to any amount of the active ingredient (page 16, lines 20-25 of the specification)."

The Applicants respectfully submit that page 16, lines 20-25, of the specification does not support the position that "dosing unit" is open to any amount of the active ingredient. This portion of the specification defines dosing unit as containing enough active ingredient to release a therapeutically effective amount of active ingredient. Page 16, lines 20-25, of the specification reads as follows:

> In this patent application the expression 'dosing unit' is understood to mean a pharmaceutical formulation that contains a defined amount of active ingredient and that releases this following the one-time administration in patients over a predetermined period of time in a therapeutically effective amount. [underscoring added]

Thus an "amount sufficient for a dosing unit" is at least a therapeutically effective amount. Since a "therapeutically effective amount" is not just "any amount," but must be enough to provide a therapeutic benefit, Meese must enable the production of enough of the compound of claim 35 to use in a dosing unit. That is, Meese must enable the production of a therapeutically effective amount of the compound of claim 35 that is above 97% pure by weight. As explained in the Amendment filed April 1, 2009, Meese fails to do this.

In view of the above, it is respectfully requested that this rejection be withdrawn.

**The rejection under 35 U.S.C. §103(a)**

Claims 35-39 and 70-72 were rejected as being obvious over Meese.

This rejection is premised on the claims being read as directed to pharmaceutical compositions. As discussed above, this is not a reasonable interpretation of the present claims. Accordingly, it is respectfully requested that this rejection be withdrawn.

Nevertheless, the Applicants would like to address certain comments in the Office Action relating to this rejection. At page 5, the Office Action stated:

> It is also obvious to obtain a highly pure hydroxymethylphenyl ester. Purification techniques such as chromatography are well known in the art and one skilled in the art would find it obvious to purify the compound after completing the synthetic procedure for its preparation.

Further at page 5, the Office Action argued that routine techniques could be used to purify the compound of Meese: "Furthermore a synthetic product can be purified via chromatographic techniques to produce a pure compound. Doing so is routine and is commonly performed in order to properly identify the product by spectroscopic methods."

These comments ignore the fact that Applicants have already tried such routine methods and have shown that they fail. See the specification, page 3, lines 10-20, where the Applicants described the results of their attempts to purify therapeutically effective amounts of the compound disclosed in Meese by conventional methods:

> Even extensive trials to purify the high purity base from the product mix in the amounts required for pharmaceutical purposes using conventional procedures remained unsuccessful.
> A purification by crystallization is eliminated because the bases of the general Formula I, or example, fesoterodine, are present as viscous oils according to the manufacturing process described in EP 1 077 912 and up to now are not able to be crystallized from the product mix.
> Even attempts to purify by distillation did not lead to the desired success.

Additionally, the Applicants also note that the Office Action, at page 5, stated:

> Applicants have argued that Meese fails to disclose the purity of the obtained compositions. Examiner does not find the above argument persuasive because the applicants are claiming a compound, not a composition, and a single compound is inherently pure.

The Applicants understand this passage to be stating that the claims are directed to a pure compound. The Applicants agree that the claims are directed to a pure compound but do not understand how that has any bearing on what Meese discloses so as to lead to a conclusion that the Applicants' argument that Meese fails to disclose a compound having the purity and amount claimed is not persuasive. The contents of Meese are what they are, irrespective of the Applicants' claims.

The time for responding to the Office Action was set for September 15, 2009. Therefore, it is believed that this response is timely. If this is in error, please treat this response as containing a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this paper and charge any corresponding fees to Kenyon & Kenyon's Deposit Account No. 11-0600.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with the filing of this paper, or any defect seen to be remaining in this application after the filing of this paper. The Director is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully Submitted,

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